

### REMARKS

In the Office Action, the Examiner rejects Claim 10 for lack of sufficient antecedent support for the claim limitation of "the control unit" in line 1 of the claim. The Applicant thanks the Examiner for noting this discrepancy and hereby amends Claim 10 to properly introduce "a control unit." The Applicant further notes that Claim 8 is amended by this paper to correct a possible indefiniteness issue with respect to the analysis gas delivery line introduced in Claim 2.

The Examiner also rejects Claims 1-4, 6, 8-10, 16, and 26 under 35 U.S.C. § 102(e) as being anticipated by Hole et al., U.S. Publication No. 2004/0081580. The Applicants have carefully reviewed the Hole et al. reference and notes that neither the prior art described in Hole et al. or the indicated invention disclosed by Hole et al. teach "... establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic body..." (Claims 1 & 16).

More particularly, both the prior art and the indicated invention described and illustrated in Hole et al. involve the entire systemic circulation of the person or animal receiving treatment. For example, in the described prior art and first embodiment of the Hole et al. device, blood is obtained from the patient, treated with nitric oxide (NO), and returned to the patient. The treatment with nitric oxide can be utilized for example, to reduce whole body bacterial contamination by pathogenic or toxic substances. Both the described prior art and indicated invention of Hole et al. utilize concentrations or dosages of nitric oxide in amounts appropriate for clinical efficacy but to avoid the undesired effects of excessive levels of nitric oxide, noting the relatively short half-life of nitric oxide when entrained in blood. Note is also made of the potential problems of oxidation of nitric oxide when exposed to molecular oxygen. Hole et al. also describes an embodiment illustrated by Figure 10 wherein "the valve 264 allows a precise amount of nitric oxide gas composition to be delivered through the gas delivery line 18, which delivers the nitric oxide to the patient's breathing orifice(s). The pressure sensor 280 is designed to deduct a drop in pressure and the gas delivery line 18, when the patient initiates a breath. "(See paragraph 54).

The Applicant respectfully notes that Hole et al. and the described prior art clearly do not anticipate establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic

body as in the Applicant's claimed invention. In contrast, in the prior art described in Hole et al. and in the described invention, the blood having been dosed with nitric oxide is explicitly returned or provided to the general systemic circulation with no mention made of isolation of any portion thereof.

Further, the treatment with nitric oxide in the Hole et al. reference is clearly provided as a physiologically active substance to suppress, for example, undesired bacteriological infection. This is in clear contrast to the Applicant's invention reciting "... wherein the device further comprises first means for feeding an analysis gas into said artificial circulation..." (Claims 1 & 16) or "...an analysis gas delivery line..." (Claim 26). Thus, not only does the Hole et al. reference fail to disclose establishing the artificial circulation isolated from the blood circulation of the systemic body, Hole et al. also does not anticipate provision for feeding an analysis gas, such as nitrous oxide into said artificial circulation. Rather, Hole et al. is clearly focused on feeding a physiologically reactive gas into the patient's systemic circulation where reactive gas (NO) provides treatment for a condition, such as for suppression of undesired biological activity. Thus, the Applicant believes that the use of nitric oxide in the Hole et al. reference is more properly characterized as a treatment gas rather than the analysis gas of the Applicant's claimed invention. Thus, the Applicant believes that Claims 1-4, 6, 8-10, 16 and 26 are not properly anticipated by the Hole et al. reference and the Applicant respectfully requests that the rejection under 35 U.S.C. § 102(e) in view of the Hole et al. reference be withdrawn.

The Examiner also rejects Claims 1-4, 6, 8-10, 16, and 26 under 35 U.S.C. § 102(e) as being anticipated by Kamibayashi et al. U.S. Patent No. 6,555,058. The Applicant has carefully reviewed the Kamibayashi et al. '058 reference and notes that the '058 reference fails to disclose "... establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic body ..." (Claims 1 & 16) or "... means for feeding an analysis gas into said artificial circulation ..." (Claims 1 & 16) or "...an analysis gas delivery line..." (Claim 26) as in the Applicant's claimed invention.

More particularly, the '058 reference is concerned with various systems and methods for monitoring nitric oxide (NO) during hemodialysis. The '058 reference notes the clinically indicated link between nitric oxide concentration and hypotension and hypoxia, particularly in

dialysis. The '058 reference is directed to monitoring the nitric oxide concentration as an indicator of potential problems with hypotension and/or hypoxia for the dialysis patient. When excessive levels of nitric oxide are detected, the various embodiments disclosed in the '058 reference are adapted to, for example, provide additional oxygen to control the nitric oxide concentration. While nitric oxide is in a sense analyzed or monitored, nitric oxide is clearly not provided as an analysis gas in any of the embodiments of the '058 reference. Rather the NO in the '058 is naturally occurring in the patient and is monitored, but not provided.

The first means 10 asserted by the Examiner in the Office Action as corresponding to a first means 10 for feeding an analysis gas into the artificial circulation is simply described in the '058 reference as "a port connector 10 at the end of the arterial blood side circuit 4 and as connected to a blood inflow port 12 of a chemodialyzer 11 as dialyzing means." It is clear from the description of the '058 reference that this connector port 10 is clearly not configured for providing an analyzing gas particularly nitric oxide. In contrast, the '058 reference is clearly directed to monitoring and mitigating the natural occurrence of nitric oxide during dialysis and clearly does not anticipate or suggest adding nitric oxide to the patient's blood. Nitric acid can also clearly not be considered an analyzing gas due to the physiologic activity of nitric acid entrained in the systemic blood. The Applicant further notes that the arterial blood side circuit 4 connected to the port connector 10 conveys blood on the arterial side and not an analysis gas as in the Applicant's claimed invention. Further, the '058 reference clearly fails to disclose establishing an artificial circulation isolated from the systemic circulation. Rather, the dialysis performed in the various embodiments of the '058 reference clearly returns the blood treated by dialysis to the systemic circulation. The Applicant thus believes that Claims 1-4, 6, 8-10, 16, and 26 are not anticipated under the requirements of 35 U.S.C. § 102(e) by the '058 reference and respectfully request that the rejection be withdrawn.

The Examiner further rejects Claims 5 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Hole et al. in view of Burton WO 0143804. The Applicant has carefully reviewed the Burton reference and notes that Burton describes only a breathing mask with built-in sensors for monitoring various physiological parameters of the patient. The described sensors can comprise one or more of oximetry sensors, position sensors, eye movement sensors, electroencephalogram sensors, electrocardiogram sensors, microphones, blood pressure sensors,

oxygen saturation sensors, temperature sensors, etc. However, Burton in no way discloses or suggests "...establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic body..." or "...means for feeding an analysis gas into said artificial circulation...". As previously noted, the Applicant believes that Hole et al. fails to disclose the above limitations recited in the base Claim 1 and further that Claim 5 properly further defines the claimed invention. The Applicant believes that the combination of Hole et al. and Burton fail to disclose the limitations of the base Claim 1 or Claim 5, depending therefrom. Further, the Applicant believes that the combination of features recited in Hole et al. and Burton fail to teach or to suggest the combination of features recited in Claim 15, namely "...establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic body..." or "...means for feeding an analysis gas into said artificial circulation...".

The Examiner also rejects Claims 7 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Hole et al. in view of Patterson et al. (U.S. Publication No. 2003/0095892). The Applicant has also carefully reviewed the Patterson et al. reference and notes that Patterson discloses an apparatus for supplemental blood oxygenation which in one embodiment develops an oxygen super-saturated fluid that is further mixed with blood to form a supplementally oxygenated blood supply that is returned for delivery to the patient. Again, Patterson et al. fails to disclose "...establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial circulation being isolated from the blood circulation of the systemic body..." (Claims 1 and 17). Patterson et al. is adapted to utilize oxygen gas, however, the oxygen gas is utilized to oxygenate blood and not as an analysis gas.

As previously noted, Hole et al. fails to disclose establishing and maintaining an artificial circulation or means for feeding an analysis gas into said artificial circulation. The Applicant further believes that the combination of Hole et al. with Patterson et al. fails to teach or suggest the combination of features recited in the base Claim 1. The Applicant believes that Claim 7 depending therefrom is patentable due partly to its dependence on Claim 1. The Applicant further believes that the combination of features recited in Claim 17 including "...establishing and maintaining an artificial circulation in a target area of a human or animal body, said artificial

circulation being isolated from the systemic blood circulation of the body, further comprising first means for feeding an analysis gas into said artificial circulation...", is also patentable under the requirements of 35 U.S.C. § 103(a) over Hole et al. and Patterson et al. The Applicant thus respectfully requests that the rejection of Claims 7 and 17 be withdrawn.

The Examiner also rejects Claims 11-14 under 35 U.S.C. § 103(a) as being unpatentable over Kamibayashi et al. in view of Senning et al. (U.S. Patent No. 3,065,748). The Applicant has carefully reviewed the Senning et al. '748 reference and notes that Senning et al. discloses a blood oxygenation apparatus adapted to oxygenate blood and remove excess oxygenation that may be exhibited by entrained bubbles of oxygen within the blood. Blood issues from a patient as indicated by arrow 1 and is returned to the patient as indicated by arrow 11. Senning et al. offers no teaching or suggestion that the drawing and returning of blood from the patient is anything other than from and back to the systolic circulation. Senning et al. clearly does not disclose or suggest establishing and maintaining an artificial circulation said artificial circulation being isolated from the systolic blood circulation as in the Applicant's base Claim 1.

Senning et al. does disclose exposing the oxygenated blood in a vessel 5 containing a rigid body 6 to a mixture of oxygen and nitrous oxide. "In the embodiment shown, it was assumed that laughing gas is administered as a narcotic." It is then supplied to the vessel 5 in which it can dissolve in the blood. At the same time, it fulfills another function, namely that of decreasing the partial pressure of the oxygen in the vessel so that diffusion of the content of the oxygen bubbles out of the blood is facilitated. Thus, the nitrous oxide as used in the Senning et al. apparatus is partially in the well known use as an analgesic and further to facilitate removal of entrained oxygen bubbles in the oxygenated blood by reducing the partial pressure of O<sub>2</sub> in the vessel. Senning et al. clearly does not disclose use of nitrous oxide as an analysis gas as in the Applicant's claimed invention. Senning et al. does not even analyze the nitrous oxide by simply delivers it. As previously noted, the Applicant believes that Kamibayashi does not disclose the invention recited in the base Claim 1. The Applicant notes that the combination of Kamibayashi and Senning et al. also fails to disclose or suggest either the limitations of the base Claim 1 or of Claims 11-14 depending therefrom. The Applicant respectfully request that the rejections of Claims 11-14 be withdrawn.

Appl. No. : 10/670,999  
Filed : September 25, 2003

#### SUMMARY

The Applicant believes that the subject application is in a condition ready for allowance and respectfully requests prompt issuance of a notice of allowability. The Applicant believes that this paper is fully responsive to the objections and rejections made by the Examiner in the Office Action, however should there remain any further impediments to the allowance of this application that might be resolved by telephone conference the Examiner is respectfully requested to contact the Applicant's undersigned representative at the indicated telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 27, 2007

By: 

James W. Ausley  
Registration No. 49,076  
Agent of Record  
Customer No. 20,995  
(951) 781-9231

3446818  
022007